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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,257	10/19/2000	Philip W. Miller	38-21(15771)B	7102

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EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/692,257	MILLER ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 8/31/2006 to the Office action has been entered. Claims 1 and 8-13 are pending.

1. Claims 1 and 8-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any polynucleotide. The specification discloses many potential uses for the polynucleotide including identifying promoters involved in gene regulation (pg. 37, lines 13-27 to pg. 38, lines 1-6), determining whether a plant contains a mutation (pg. 14, lines 10-27 to pg. 15, lines 1-12 and pg. 38, lines 7-27), and acting as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (pg. 46, lines 4-46). These are non-specific uses that are applicable to polynucleotides in general and not particular or specific to the polynucleotide claimed. Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be identified as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and genes does not constitute a specific and substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific

due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polynucleotides such that another non-asserted utility would be well established for the compounds.

The response argues that the nucleic acid molecules provided are used as a marker of cold tolerance (See pg. 34, line 21 to pg. 35, line 8 of the specification). The response also indicates Example 1, which describes the cDNA library from young maize seedlings that have been subjected to cold treatment (See pg. 88 of the specification). However, there is no statement that SEQ ID NO: 1 is used as a marker of cold tolerance in Example 1 and throughout the specification, Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112, first paragraph (Enablement)

2. Claims 1 and 8-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a "specific or substantial" asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to a substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement. The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims broadly any variants and fragment of SEQ ID NO: 1 DNA, predicting protein structure from sequence data

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely difficult. It would require significant study to identify the actual function of the maize protein, and identifying a use for this protein would be an inventive, unpredictable and difficult undertaking in itself. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. the sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites, and determinants of antigenicity. These regions can tolerate only relatively conservative substitute or no substitute (See Wells, Biochemistry, 1990, 29, pg. 8509-8517; Ngo et al. The Protein Folding Problem and Tertiary Structure Prediction, pg. 492-495).

This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

The art is extremely unpredictable with regard to protein function in the absence of reliable information regarding the protein function.

Working Examples

The specification has working example in which cDNA libraries are constructed but the working example lacks sufficient information regarding how the nucleic acid molecule that encodes a maize protein or fragment comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement is purified.

Guidance in the Specification.

Applicant has provided little or no guidance beyond the presentation of sequence data to enable one of ordinary skill in the art to determine the positions in the protein, which are tolerant to change (e.g. amino acid substitutions or deletions). Thus, the specification did not teach any actual function of the nucleic acid sequence of SEQ ID NO: 1 and its complement.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Although the specification outlines art-recognized procedures for producing and screening for active muteins, this is not an adequate guidance as to the nature of active derivatives that may be constructed, but is an invitation to the artisan to use the current invention

as a starting point for further experimentation. The art recognizes that function cannot be predicted from structure alone (Bork, Genome Research 2000, 10, pg. 398-400; Skolnick et al. Trends in Biotech, 2000, 18(1), pg. 34-39, especially p. 36 at Box 2; Doerks et al. Trends in Genetics, 1998, 14: pg. 248-250; Smith et al, Nature Biotechnology, 1997, 15: pg. 1222-1223; Brenner, Trends in Genetics, 1999, 15: pg. 132-133; Bork, Trends in Genetics, 1996, 12: pg. 425-427). Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims, the claims fail to recite any structural or functional limitations, undue experimentation would be required by the skilled artisan to make and/or use the claimed invention in its full scope.

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the presence of a working example which does not address the issue of the utility of the claimed nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement. It is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

The response argues that the specification provides seven examples to enable one of ordinary skill in the art to make and use the invention commensurate in scope with the claims. In the seven examples, there is no mention that one of ordinary skill in the art to make and use SEQ ID NO: 1.

The response also argues that the specification describes amino acid sequences derived therefrom, antibodies, construct and methods related thereto, but there is no specific statement regarding SEQ ID NO: 1.

Thus, the rejection is maintained.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to a maize protein. The breadth of enablement is not commensurate in scope with the claims. The specification discloses very narrow working examples as compared to the wide breath of the claims at issue. Furthermore, EST technology is highly unpredictable. Thus, the teachings set forth in the specification provides no more than a "plan" or "invitation' for those skilled in the art to experiment using the technology in other type of cells.

The response does not have argument regarding what is the nucleic acid sequence which encodes the fragment thereof recited in claim 1. The rejection is maintained.

Summary

4. No claims are allowable.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung
November 2, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
11/2/06